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Regulatory Framework of Genetically Modified Plants in Japan

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ABSTRACT

Japan regulates genetically modified plants within a framework of safety evaluations related to their consumption as food or animal feed and their impact on biological diversity. The evaluations are conducted by the Food Safety Commission under the Cabinet Office, the Agricultural Materials Council under the Ministry of Agriculture, Forestry, and Fisheries (MAFF), and the Biodiversity Impact Assessment Group under the MAFF and the Ministry of the Environment. Japan adopts the point of view that genetic modification technology shall be "used with close attention to its safety". As of 2006, genetically modified plants are not cultivated in Japan. However large amounts of genetically modified crops, such as soybeans, corn, rapeseed, and cotton, are imported into Japan as commodities. It is ironic that the special attention given to genetically modified components in the labeling requirements for processed foods may be impeding public acceptance of genetic modification.

Keywords: GMO; Regulation; Food; Feed; Environment; Public acceptance (PA).

INTRODUCTION

Genetic modification technology holds hopes for providing technological solutions to social issues on the one hand and uncertainties on the other because it is a new technology with which we have little historical experience. Society should recognize that although this technology may be beneficial to humans, its impact on the health of humans and animals alike, and particularly on the environment, also needs to be scientifically evaluated so that the technology can be used in conjunction with appropriate control systems. In order for the government to respond to such demands in a responsible manner, it must establish a framework and provide it with laws and other regulatory means as well as adopting approaches and specific methods to perform impact assessments. This report describes the regulatory framework for genetically modified plants in Japan.

Japan's Basic Point of View on the Regulation of Genetically Modified Plants

Japan has adopted the position that genetic modification technology shall be "used with close attention to its safety". This means that it will use genetic modification technology with an understanding of its potential and importance and with valid confirmation of its safety to the environment and health based on the latest scientific findings. Furthermore, it is the government's basic policy to disclose accurate information to the public in an appropriate manner and ask the public to participate in discussions on safety issues. This policy conforms to global trends. Based on such a point of view, the MAFF promotes studies of genetic modification for the purpose of putting genetically modified organisms to practical use. The ministry also conducts safety evaluations during development as well as use. In response to criticisms that information on genetic modification technology has been scarce and difficult to understand, the government plans to conduct surveys so that it can provide accurate

and easy-to-understand information. The results of the surveys will be used for public communications and will be reflected in government policies to promote public understanding of the importance and safety of genetic modification technologies.

Japan's Regulatory Programs for Genetically Modified Plants

In Japan, genetically modified plants are examined for their safety both as food and as feed, as well as their impact on biodiversity.

(1) Safety as food

The safety of genetically modified plants for food use is examined according to the ***Basic Law for Food Safety*** by the Food Safety Commission under the Cabinet Office. Information, however, is disseminated by the Ministry of Health, Labor, and Welfare. Food derived from genetically modified plants may be imported for market distribution only if the Food Safety Commission has confirmed its safety. Stacks, combinations of different events, are also subject to examination. Major items examined include:

- ∞ The safety of host plants, genes used for modification, and vectors;
- ∞ Genes used for modification;
- ∞ The safety of proteins produced as a result of genetic modification, particularly their allergenicity (allergenicity is assessed by the ease of breakdown of proteins and comparisons with amino acid sequences of known allergens);
- ∞ The potential for unexpected transmutations as the result of genetic modification; and
- ∞ The potential for significant changes in the nutrient content of food.

As of August 15, 2006, the Commission had confirmed 75 food items to be safe.

(2) Safety as animal feed

The safety of genetically modified plants for use in animal feed is examined according to the ***Law Concerning the Safety and Quality Improvement of Feed*** (known as the ***Feed Safety Law***) by the Agricultural Materials Council under the MAFF. Feed derived from genetically modified plants may be imported and sold only if the Agricultural Materials Council has confirmed its safety. Stacks are excluded from the examination. Major items examined include the following:

- ∞ Any significant changes in components of feed in comparison with existing crops; and
- ∞ The potential for the production of toxic substances (ranging from the potential production of toxic substances in genetically modified plants to the potential production of new toxic substances in animals by the action of a genetically modified component on the metabolic systems of the animals).

As of March 31, 2006, the Council had confirmed the safety of 47 items.

(3) Impact on biodiversity

As a result of the November 21, 2003 ratification of the Cartagena Protocol on Biosafety of the Convention on Biological Diversity, which came into effect internationally on September 11 of that year, Japan has developed a legal basis framework with respect to the potential impacts of genetic modification on biodiversity. Although a protocol of an international convention is not binding in itself, signatories to the convention are required to develop a regulatory framework using domestic laws to ensure that the protocol rules are observed and implemented in their countries. Japan enacted the ***Law Concerning Securing of Biological***

Diversity by the Regulation of the Use of Genetically Modified Organisms (known as the ***Cartagena Law***) on February 19, 2004 to implement assessment requirements to deal with the impacts of genetically modified organisms on biodiversity.

The impacts of genetically modified plants on biodiversity are examined according to the above-mentioned ***Cartagena Law*** by the Biodiversity Impact Assessment Group under the joint jurisdiction of the MAFF and the Ministry of the Environment. Genetically modified plants are divided into two classes according to use: class 1 plants are used outdoors, while class 2 plants are used in an indoor environment equipped with measures to prevent their spread. So far there have been no examples of class 2 plants; all plants classified to date have been class 1. Class 1 plants are further divided into segregated cultivation for limited growing periods and general cultivation.

Japan allows only plants which have been confirmed to be safe by the Biodiversity Impact Assessment Groupfor general cultivation outdoors and for market distribution. Ornamental foliage plants, which are not used for food or feed, are also subject to examination, as well as stacks. Major items examined include the following:

- ∞ Competitive superiority;
- ∞ Potential production of toxic substances; and
- ∞ Cross-fertility.

As of September 5, 2006, 31 items had been approved for general cultivation in Japan.

Table 1 summarizes the framework for the evaluation of genetically modified plants for their safety as food and feed as well as their impacts on biological diversity.

Current general acceptance of genetically modified plants in Japan

As of 2006, there is no cultivation of genetically modified plants in Japan. A certain type of genetically modified carnation is sold, which used to be cultivated in Japan but is now grown in Colombia and imported into Japan. One of the reasons that genetically modified plants are not cultivated in Japan is the lack of public acceptance of them for food and cultivation.

Nevertheless, Japan, the world's largest importer of agricultural products, imports large amounts of genetically modified soybeans, corn, rapeseed, and cotton as commodities, and uses them in animal feed, food oils, and processed food. The public is generally unaware of this fact.

Labeling problem

Labeling regulations require the disclosure of any genetically modified ingredients, such as soybeans, used in processed food. Labeling of non-use of such ingredients is optional. In reality, a large majority of labels emphasize the "non-use" of genetically modified ingredients. Expressions such as "no genetically modified ingredients" appear to be used as a commercial catchword. This practice may be persuading consumers that genetic modification is harmful.

Issues

Economidis (2006) of the European Commission summed up the results of 20 years of studies on the safety of GMOs by saying "GMOs as well as non-GMOs, are neither inherently risky nor inherently safe; whether or not the application with an organism poses a risk to human health or the environment depends on the

characteristics of the organism and the circumstances of the application", and acknowledged that risks associated with GMOs were no greater than risks inherent in the host organisms. Public acceptance, however, is a prerequisite for the use of genetically modified plants. Regulations are relatively loose in the United States where the acceptance of GMO crops is well advanced. In Japan, however, the lack of public tolerance has resulted in a relatively stricter regulatory framework. This strictness, in turn, has created the undeniable impression that the GMO plants are dangerous. A dilemma of increasingly tighter controls and the reluctance to accept GMO organisms on the part of the public remain an issue.

REFERENCES

Economidis, I. 2006. Two decades of EC sponsored research on safety of GMOs. Proceedings of the 9th International Symposium on the Biosafety of Genetically Modified Organisms. 42-44.

Table 1. Japanese framework for an examination of the safety of genetically modified plants for food and feed use and the assessment of their impacts on biological diversity

	Examining body	Jurisdiction	Governing law	Major item examined
Safety as food	Food Safety Commission	Cabinet Office	Basic Law on Food Safety	∞ Safety of host plants, genes used for modification, and vectors ∞ Genes used for modification ∞ Safety of proteins produced as a result of genetic modification, particularly their allergenicity. (allergenicity is assessed by the ease of breakdown of proteins and comparisons with amino acid sequences of known allergens) ∞ Potential for unexpected transmutations as the result of genetic modification ∞ Potential for significant changes in the nutrient content of food
Safety as animal feed	Agricultural Materials Council	Ministry of Agriculture, Forestry, and Fisheries	Law Concerning the Safety and Quality Improvement of Feed (the Feed Safety Law)	∞ Any significant changes in components of feed in comparison with existing crops ∞ Potential for the production of toxic substances (ranging from the potential production of toxic substances in genetically modified plants to the potential production of new toxic substances in animals by the action of a genetically modified component on metabolic system of the animal)
Impact on biodiversity	Biodiversity Impact Assessment Group	Ministry of Agriculture, Forestry, and Fisheries Ministry of the Environment	Law Concerning Securing of Biological Diversity by the Regulation of the Use of Genetically Modified Organisms	∞ Competitive superiority ∞ Potential production of toxic substances ∞ Cross-fertility